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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,300	08/21/2001	Todd Lewis Talarico	35780/233666 (5780-5)	8297

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1645

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J

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/934,300	Applicant(s) Talarico et al.
	Examiner S. Devi, Ph.D.	Art Unit 1645
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>three</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Apr 11, 2003</u></p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>		
Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-19</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) <u>1-11</u> is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>12-19</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>		
Application Papers <p>9) <input checked="" type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
Priority under 35 U.S.C. §§ 119 and 120 <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). <p>*See the attached detailed Office action for a list of the certified copies not received.</p> <p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p> <p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
Attachment(s) <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4 & 5.</u></p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>		

DETAILED ACTION

Election

- 1) Acknowledgment is made of Applicants' election filed 04/11/03 (paper no. 7) in response to the restriction requirement mailed 03/31/03 (paper no. 6). Applicants have elected invention II, claims 12-19, without traverse.

Status of Claims

- 2) Claims 1-19 are pending.

Claims 1-11 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

The elected claims 12-19 are under examination. A First Action on the Merits is issued for these claims.

Information Disclosure Statements

- 3) Acknowledgment is made of Applicants' information disclosure statements filed 12/11/01 (paper no. 4) and 01/07/03 (paper no. 5). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 8).

Specification - Informalities

- 4) The specification is objected to for the following reasons:

The use of the trademark in the instant specification has been noted. For example, 'Posidyne' under the section 'Experimental'. The recitation should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix 1. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

- 5) Claims 12-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

- (a) Claim 12 is vague and confusing in the use of the abbreviation in the claim language: "aPEG", because it is unclear what does it stand for. It is suggested that the abbreviation be recited

as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(b) Claim 13 is vague and confusing in the use of the abbreviation in the claim language: "POE", because it is unclear what does it stand for. It is suggested that the abbreviation be recited as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(c) Claim 16 is vague and confusing in the use of the abbreviation in the claim language: "EU", because it is unclear what does it stand for. It is suggested that the abbreviation be recited as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(d) Claim 12 is vague and indefinite in the recitation "chemically modified hemoglobin solution", because it is unclear whether what is modified is the solution or the hemoglobin in the solution.

(e) Claim 12 is vague and indefinite in the recitation "substantially free", because it is unclear what is encompassed in the limitation. It is unclear what degree of contamination does this limitation permit. The term "substantially" is a relative term which renders the metes and bounds of the claims indeterminate. The specification does not appear to provide a standard for ascertaining the requisite degree of contamination and therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the claim.

(f) Analogous rejection applies to claim 15.

(g) Claim 17 is vague, indefinite and confusing in the recitation "micron micron", because it is unclear what unitage does it represent.

(h) Claim 19 lacks proper antecedence in the recitation "combining means". Claim 18 depends indirectly from claim 12, which already recites 'a combining means'. It is suggested that Applicants provide proper antecedent basis by replacing the limitation with --the combining means--.

(i) Claim 17 contains the trademark/trade name "Posidyne". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982)*. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product and since the composition of the product can change from time to time without any change in the trade name. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus,

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a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe 'Nylon 66 Posidyne' and, accordingly, the identification/description is indefinite.

(j) Claims 13-19, which depend directly or indirectly from claim 12, also stand rejected under 35 U.S.C. § 112, second paragraph, because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

6) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) Claims 12-16 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 2000).

Talarico *et al.* taught a method of preparing a substantially pure PEG or POE modified stroma free hemoglobin. The method comprised treatment with ethanol, filtration through BioSEP S-400 and SuperDex 75 columns and filtering through a Whatman Anodisc membrane filter and passing through CNBr-Sepharose column of resins.

Claims 12-16 and 18 are anticipated by Talarico *et al.*

Rejection(s) under 35 U.S.C. § 103

8) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

9) Claims 12, 17 and 19 are rejected under 35 U.S.C. § 102(b) as being unpatentable over Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 2000) in view of Feola *et al.* (US 5,439,882).

The teachings of Talarico *et al.* are described above, which do not disclose the use of the specific filter recited in claim 17.

However, Feola *et al.* taught the use of a Posidyne 0.20 micron filter to further remove microbial contaminants from hemoglobin preparations (see Example 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Feola's Posidyne 0.20 micron filter in place of Talarico's filter to produce the instant invention with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of further removing microbial contaminants from Talarico's preparation. With regard to aseptic joining, that Talarico's method as modified by Feola *et al.* involves sterile formulation is implicit from the teachings of prior art.

Claims 12 and 17 are *prima facie* obvious over the prior art of record.

Remarks

- 10) Claims 12-19 stand rejected.
- 11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day and seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the

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Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

June, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER